



PTO/SB/08A (08-03)

Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/658,219
Filing Date	September 8, 2003
First Named Inventor	Bruce Joseph Roser
Art Unit	1646
Examiner Name	Not yet assigned
Attorney Docket Number	GJE-6089D2

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code* (if known)			
✓	U1	US-4,495,175 A	Chavin <i>et al.</i>	1-22-1985	
✓	U2	US-4,758,657 A	Farb <i>et al.</i>	7-19-1988	
✓	U3	US-4,806,343 A	Carpenter <i>et al.</i>	2-21-1989	
✓	U4	US-4,891,319 A	Roser	01-02-1990	
✓	U5	US-5,364,756 A	Livesey <i>et al.</i>	11-15-1994	
✓	U6	US-5,576,291	Curtis	11-19-1996	
✓	U7	US-6,649,386 B2	Roser	11-18-2003	
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
		Country Code* - Number* - Kind Code* (if known)				
✓	F1	EP 0 314 095 A1 9	05-03-1989	Rorer International (Overseas) Inc.		
✓	F2	EP 0 475 409 A2 v	03-18-1992	Lifecell Corporation		
✓	F3	WO 87/00196 ✓	01-15-1987	Quadrant Bioresources Limited		
✓	F4	WO 94/07510 A1 >	04-14-1994	Kabi Pharmacia AB		
✓	F5	WO 95/01804 2	01-19-1995	Kabi Pharmacia AB		
✓	F6	WO 95/07713 ✓	03-23-1995	Baxter International		
	F7					

Examiner
SignatureDate
Considered

3-17-06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/658,219	
			Filing Date	September 8, 2003	
			First Named Inventor	Bruce Joseph Roser	
			Group Art Unit	1646	
			Examiner Name	Not yet assigned	
Sheet	2	of	2	Attorney Docket Number	GJE-6089D2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R1	Cleland, J.L. et al. (ed) "Design and Development Strategies" Chapter 1 in Formulation and Delivery of Proteins and Peptides, American Chemical Society Symposium Series (1994) 567:1-19.	
	R2	Roser, B. et al. "Trehalose Drying: A Novel Replacement for Freeze-Drying" BioPharm (September 1991) vol. 4(8):47-53.	
	R3		
	R4		
	R5		
	R6		
	R7		
	R8		
	R9		
	R10		
	R11		
	R12		
	R13		

Examiner Signature		Date Considered	3-17-06
--------------------	--	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.